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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/534,038	03/24/2000	Scott J. Wolf	7883.0004-02	2278

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EXAMINER	
BIANCO, PATRICIA	

ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 07/02/2004

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/534,038	WOLF ET AL.	
	Examiner	Art Unit	
	Patricia M Bianco	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *18*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. In the amendment filed 02/05/04, claims 43-47 were cancelled. Claims 15-42 remain pending.

Inventorship

2. The request to correct the inventorship of this nonprovisional application under 37 CFR 1.48(a) is deficient because:

An oath or declaration by each actual inventor or inventors listing the entire inventive entity has not been submitted.

The statement of facts by an inventor or inventors to be added or deleted that explicitly states that the inventorship error occurred without deceptive intent on his or her part or cannot be construed to so state was not included.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000.

Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

3. Claims 15-20, 24-27, 29-34 & 38-42 are rejected under 35 U.S.C. 102(e) as being anticipated by Knudson et al. (5,944,019). Knudson discloses a method for performing coronary artery bypass, which results in providing direct blood flow between a heart chamber and a coronary vessel (col. 13, lines 1-11). A channel is established between a heart chamber and a coronary artery. A conduit (i.e. implant) may be placed within the formed channel to maintain a fluid pathway during contractions of the heart. The conduit is disclosed to be any suitable device, such as a stent (col. 9, lines 58-61). Knudson discloses a method wherein a wall of the coronary artery is incised by standard technique, making a channel through the coronary walls, inherently passing through the anterior and posterior walls, to then move through the heart wall into the heart chamber. The channel can be made by standard technique, such as a laser, puncturing with a trocar, incising with a scalpel, electrosurgically with an electrosurgical cutting tool, laser or RF ablation, blunt dissection, etc. (col. 21, line 55-col. 22, line 22; col. 23, line 45-col. 24, line 5). Knudson further teaches that the method can be carried out using a balloon catheter, wherein the catheter has a stent, which is expandable, disposed thereon. The catheter is advanced to the channel formed in the heart wall and the stent is deployed in place (col. 25, lines 36-64). With respect to the recitation in claim 29 that the implant does not extend substantially along an axial direction of the

vessel, Knudson shows the implant (12', 61) extending within the passageway offset from the vessel's axis in figures 5 & 14D respectively.

4. Claims 15-20, 24-29, & 38-42 are rejected under 35 U.S.C. 102(e) as being anticipated by LaFontaine et al. (6,092,526). LaFontaine discloses a method for performing chamber-to-artery bypass between a coronary artery and a heart chamber. LaFontaine teaches that a cutting device can be used to form a lumen (i.e. channel) through heart tissue starting from the coronary artery (col. 4, lines 36-41). Since one is starting the lumen through the coronary artery, it is inherent that the device would pass first through the anterior and then through the posterior wall of the vessel and through the heart wall. LaFontaine discloses creating a lumen in the wall using an instrument such as a cutting or debulking device, boring device, rotating blade,, RF ablation, laser or any other suitable mechanical or energy device (col. 4, lines 11-35). LaFontaine further teaches that a stent may be placed in the created lumen and expanded by using a catheter system (col. 5, lines 54-64). With respect to the recitation in claim 29 that the implant does not extend substantially along an axial direction of the vessel, LaFontaine shows the implant extending within the passageway offset from the vessel's axis in figures. LaFontaine et al. also discloses that the method may include delivering a drug using a suitable delivery device into the lumen formed within the wall of the heart. The substance that may be delivered includes a growth factor to enhance endothelialization in the lumen (col. 7, lines 35-53).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 21-23 & 35-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knudson et al. ('019) in view of Evans et al. (5,980,548). Knudson et al. disclose the invention substantially as claimed, see rejection supra, however, fails to disclose specifically that the implant or stent carry a substance for delivery to the heart wall, wherein the substance is for one of generating, stimulating, and enhancing blood vessel formation, and wherein the substance is chosen from angiogenesis factors and nucleic acid instructions for angiogenesis factors.

Evans et al. disclose inserts for deployment into the heart wall and where the inserts may be hollow, tubular members that are equivalent to a stent or implant, and the inserts can be coated with or contain growth factors, or a material that will provide vasculature or angiogenesis in the heart wall (col. 14, lines 15-20 & col. 16, lines 10-31). At the time of the invention, it would have been an obvious design choice to modify the stent of Knudson et al. by substituting the implant having a coating that contains growth factors or a material that will provide vasculature or angiogenesis in the heart wall as taught by Evans et al. to provide new growth of vessels and provide a lasting therapeutic effect, since substitution of parts which provide the same function would be within the level of ordinary skill in the art.

6. Claims 21-23 & 35-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over LaFontaine et al. ('526) in view of Evans et al. (5,980,548). LaFontaine et al. disclose the invention substantially as claimed, see rejection supra, however, fails to disclose specifically that the implant or stent carry a substance for delivery to the heart wall, wherein the substance is for one of generating, stimulating, and enhancing blood vessel formation, and wherein the substance is chosen from angiogenesis factors and nucleic acid instructions for angiogenesis factors.

Evans et al. disclose inserts for deployment into the heart wall and where the inserts may be hollow, tubular members that are equivalent to a stent or implant, and the inserts can be coated with or contain growth factors, or a material that will provide vasculature or angiogenesis in the heart wall (col. 14, lines 15-20 & col. 16, lines 10-31). At the time of the invention, it would have been an obvious design choice to modify the stent of LaFontaine et al. by substituting the implant having a coating that contains growth factors or a material that will provide vasculature or angiogenesis in the heart wall as taught by Evans et al. to provide new growth of vessels and provide a lasting therapeutic effect, since substitution of parts which provide the same function would be within the level of ordinary skill in the art.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA

1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claim 15 is provisionally rejected under the judicially created doctrine of double patenting over claim 85 of copending Application No. **10/681,323**. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: the applications both claim methods of providing direct blood flow between a heart chamber and a coronary vessel, comprising steps of inserting an instrument through anterior and posterior walls of the coronary vessel and a heart wall to for a passageway in the heart wall, and inserting a nonrigid implant/stent within the passageway. The only difference is that in the instant application a "nonrigid implant" is claimed to be inserted within the passageway and in 10/681,323 "a stent" is claimed to be inserted within the passageway. It is well known within the art that an implant and a stent are equivalent structures.

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other

copending application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

8. Claims 15, 16, 20 & 24-28 are provisionally rejected under the judicially created doctrine of double patenting over claims 18, 19, 25, & 33 of copending Application No. **10/617,176 (2004/0106931)**. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: the applications both claim methods of providing direct blood flow between a heart chamber and a coronary vessel, comprising steps of inserting an instrument through anterior and posterior walls of the coronary vessel and a heart wall to for a passageway in the heart wall, and inserting a nonrigid implant/conduit within the passageway. The main difference is in the instant application "an instrument" is broadly recited as being inserted into the vasculature to form a passageway in the heart wall and in 10/617,176 a "guide device", and then further a hollow needle, is recited as being inserted into the vasculature to form a passageway in the heart wall. These are obvious variants of one another that perform the same function. Also, in the instant application a "nonrigid implant" is claimed to be inserted within the passageway and in 10/617,176 "a conduit" is claimed to be inserted within the passageway. It is well known within the art that an implant and a conduit are equivalent structures.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

9. Claims 15, 16, 20, 26-30, 33, 34 & 38-42 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 17, 18, 24, 39-41, & 45-48 of U.S. Patent No. **6,638,237**. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant application & Patent '237 both claim a method of providing direct blood flow between a heart chamber and a coronary vessel, comprising steps of inserting an instrument/guide device through anterior and posterior walls of the coronary vessel and a heart wall to for a passageway in the heart wall, and inserting a nonrigid implant/conduit within the passageway. The main difference is in the instant application "an instrument" is broadly recited as being inserted into the vasculature to form a passageway in the heart wall and in Patent '237 a "guide device", and then further a hollow needle, is recited as being inserted into the vasculature to form a passageway in the heart wall. These are obvious variants of one another that perform the same function. Also, in the instant application a "nonrigid implant" is claimed to be inserted within the passageway and in Patent '237 "a conduit" is claimed to be inserted within the passageway. It is well known within the art that an implant and a conduit are equivalent structures.

Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia M Bianco whose telephone number is (703)

305-1482. The examiner can normally be reached on Monday to Friday 9:00-6:30; alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (703) 308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

June 28th, 2004

Patricia M Bianco
Primary Examiner
Art Unit 3762

PATRICIA BIANCO
PRIMARY EXAMINER